

October 12, 2011

Anastassios G. Pittas, MD, MS
Associate Professor of Medicine
Division of Endocrinology, Diabetes & Metabolism
Tufts Medical Center, Boston, Massachusetts

Re: **Data and study procedures management for proposed new trial under Renewal of R01DK076092**

PI: Anastassios G. Pittas, M.D., M.S.

Dear Dr. Pittas:

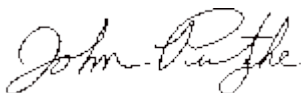
I am very happy to write this letter in support of your renewal application for your grant R01DK076092. I fully agree to provide our services with regard to the management of subject data and study conduct. StudyTrax will track all elements of trial conduct, including subject enrollment and flow through the study (e.g. scheduling of visits), capture data elements in a series of short, well-designed forms all available on-line via a secure web portal, and facilitate transfer of data into statistical packages for analysis. The software will be utilized for web-based real-time data capture, as described in the Resources section of your application. This web-based data capture is ideal for a 2-site trial, such as the one you propose. StudyTrax is presently being used at dozens of major academic research centers to support numerous NIH funded projects and is available commercially (<http://www.sciencetrax.com>).

As you mention in your application, you have successfully used StudyTrax for your recently completed trial (CaDDM) and I am glad to hear that you have been impressed with the quality of the software and the support we have provided to you. As you know, the Research Design Center at Tufts-Clinical Translational Science Institute (Tufts CTSI), which will serve as your study's Data Coordinating Center, provides technical support for the StudyTRAX application, which is also being used by other studies conducted at Tufts University. Given your familiarity with StudyTrax, we expect the set-up of the database to be straightforward and uncomplicated as the web based data entry and management system designed for the CaDDM trial will be adapted for the proposed trial in participants with type 2 diabetes.

We have provided you with a budget for setting up the database and for the standard yearly licensing, which you will include in your budget.

On behalf of all of us here at StudyTrax, it has been a pleasure working with you as part of the CaDDM trial and I look forward to further our collaboration in the new trial.

Sincerely,



John Putzke, Ph.D., M.S.P.H.
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